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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,554	11/28/2001	Andreas Manz	50225-S066.US08	1440

22918 7590 02/18/2005
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EXAMINER

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ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/995,554	Applicant(s) MANZ ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 19-45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/226,605.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/26/2002</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Interference Request

1. In Applicants' Preliminary Amendment of November 28, 2001 ("Preliminary Amendment") Applicants requested that interference proceedings be started against U.S. Patent No. 6,153,073. Applicants also stated in the Preliminary Amendment that they "will file a formal Request for Interference Under 37 C.F.R. § 1.607 in due course." To the examiner's best knowledge no such request has been filed at the time of writing of this Office action. Since there is a question of priority over limitations in claims 19, 27-32, 36, 37, and 42-44 no interference will be initiated against U.S. Patent No. 6,153,073 as it qualifies as prior art, at least in part, against the instant application.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. The instant application claims priority from application serial no.'s 09/657,772 and 08/226,605 as a continuation of these applications (page 1 of the specification); however, the instant application is actually a continuation-in-part as no support has been found in these parent applications for the following limitation in claim 19 "which one or more control devices concomitantly direct flow of material through the main channel [while sample material is moved through the sample loading channel]." In fact, the specification of the instant application (which should be same as those in 09/657,772 and 08/226,605 since they are related as continuations) teaches away from this limitation. See page 7, second full paragraph. Thus, this limitation has priority only back to November 28, 2001, which is the filing date of the instant application and the filing date of the preliminary amendment that introduces claims 19-45, which is more than one year after the effective filing date of Dubrow et al. (US 6,153,073).

Similarly, no support in either of the parent applications has been found for

- (a) the reservoirs centers of claims 27-29,
- (b) the densities of reservoirs of claims 30-32,
- (c) the additional dimensional limitations of claims 36 and 37,
- (d) embossed or etched grooves as required by claim 42, and
- (e) a separation medium or a sieving medium in the main channel as required by claims 43 and 44.

Double Patenting Rejections Based on US 6,280,589 B1

4. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073). Although the conflicting claims are not identical, they are not patentably distinct from each other because the body structure set forth in claim 19 is implicitly or directly provided by claim 3 and the transport system set forth in claim 19 is implicitly provided by claim 4. The correspondence between the elements of claim 19 and claims 3 and 4 is as follows

<u>Claim 19(body structure)</u>	<u>Claim 3</u>
microfluidic device	micromachined or etched capillary channels
body structure	planar substrate
main channel	electrolyte channel
sample loading channel	supply channel
main channel intersecting the sample loading channel	supply and drain channels intersect said electrolyte channel
sample loading channel is fluidly coupled to a source of at least one sample material and a fluid reservoir	the supply channel contains sample

Claim 19(transport system)

transport system coupled to the sample loading channel

one or more control devices which direct movement of the at least one sample material through the sample loading channel to a position proximal to the intersection of the sample loading channel and the main channel

which one or more control devices concomitantly direct flow of material through the main channel

Claim 3

electrokinetically injecting the sample

electrokinetically injecting the sample as a sample plug into said electrolyte channel by applying an electric field across the supply and drain channels

wherein said electrolyte buffer and said sample are transported electrokinetically, and further wherein immediately after said injection of said sample plug said electrolyte buffer is allowed to advance into said supply channel and into said drain channel

Even if the passage in claim 3 cited above as corresponding to the limitation to claim 19 of “which one or more control devices concomitantly direct flow of material through the main channel” is construed as not necessarily requiring concomitantly directing material flow through the main channel, it would have been obvious to one with ordinary skill in the art at the time of the invention to do so because as taught by Dubrow et al. (US 6,153,073), which implicitly discloses control means for injecting sample from a sample loading channel into main channel while concomitantly directly flow of material through the main channel, such control means will

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(a) “avoid any diffusion or leaking of the sample into the intersection during analysis,” and (b) saves time when multiple samples are analyzed. See the abstract; Figures 3, 2B, and 1A-1I; col. 13:8-15; and col. 14:52-65.

5. Claim 20 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073). Claim 19, from which claim 20 depends, has been addressed above. Electrosmotically or electrophoretically flowing an injected sample through at least a portion of the main channel while simultaneously loading an additional sample into the sample-loading channel is disclosed by Dubrow. See Figure 2B and col. 14:52-65. It would have been obvious to one with ordinary skill in the art at the time the invention was made to do so because as taught by Dubrow this will save time when multiple samples are to be processed. See col. 14:52-65. As for an instruction set for performing this activity see col. 5:33-40 in Dubrow. Furthermore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an instruction set for performing the claimed injecting step in the form of a computer program, for example, as this would be just merely automating control of the flow process.

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6. Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073). Claim 19, from which claim 21 depends, has been addressed above. Electrosmotically or electrophoretically flowing an additional injected sample through at least a portion of the main channel while simultaneously loading a further additional sample into the sample-loading channel is disclosed by Dubrow. See Figure 2B and col. 14:52-65. It would have been obvious to one with ordinary skill in the art at the time the invention was made to do so because as taught by Dubrow this will save time when multiple samples are to be processed. See col. 14:52-65. As for an instruction set for performing this activity see col. 5:33-40 in Dubrow. Furthermore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an instruction set for performing the claimed injecting step in the form of a computer program, for example, as this would be just merely automating control of the flow process.

7. Claims 27-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 4, and 17 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073). Claim 22, from which claims 27-32 depend, has been addressed above. Claim 17 of U.S. Patent No. 6,280,589 B1 appears to disclose “centers” for the supply and drain ports of about 0 microns to 3 cm. Also, Dubrow discloses the claimed reservoir centers and densities of reservoirs. See claims 9-13 of Dubrow.

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In light of these disclosures, the claimed “centers” and densities of reservoirs, barring a contrary showing, are just design choices. It would have been obvious to one with ordinary skill in the art at the time of the invention to have the reservoirs as close together as possible, such as disclosed by Dubrow, without unduly lengthening the channel lengths so that the microfluidic device can be made as compact as possible without unnecessarily increasing the distance substances have to flow and while allowing ready access to the reservoirs.

8. Claim 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073). Claim 22, from which claims 35 depends, has been addressed above. The combination of claims of 3 and 4 of U.S. Patent No. 6,280,589 B1 as modified by Dubrow (what portion is valid as prior art) does not mention having the widths and depths of the channels the same. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to do so because this will simplify manufacturing of the microfluidic device as only two aspects of a channel, the length and location, will have to be changed when a new channel is made.

9. Claim 36 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 4, and 16 of U.S. Patent No.

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6,280,589 B1 in view of Dubrow et al. (US 6,153,073). Claim 22, from which claims 36 depends, has been addressed above. Claim 16 of U.S. Patent No. 6,280,589 B1 which is directed to a device for practicing the invention of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 requires the channels to have a depth within the claimed dimension range. Claim 18 of Dubrow requires the channels to also have a dimension as claimed. It would have been obvious to one with ordinary skill in the art at the time of the invention to have a dimension as claimed since the claimed device is a microfluidic device and the channel dimensions will be scaled according to the sample volume to be processed.

10. Claim 37 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 4, and 16 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073). Claim 22, from which claims 36 depends, has been addressed above. Claim 16 of U.S. Patent No. 6,280,589 B1 which is directed to a device for practicing the invention of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 requires the channels to have a depth overlapping the claimed depth dimension range. Claim 19 of Dubrow requires the channels to also have width and depth dimension ranges as claimed. It would have been obvious to one with ordinary skill in the art at the time of the invention to have a width and a depth within the dimension ranges claimed since the claimed device is a microfluidic device and the channel dimensions will be scaled according to the sample volume to be processed.

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11. Claim 38 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073). Claim 19, from which claims 38 depends, has been addressed above. The supply and drain ports of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 correspond to the sample reservoir and waste well, respectively, of claim 38 of the instant application and thus claim 38 provides a pre-loading module as claimed.

12. Claim 39 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073) and Pace (US 4,908,112). Claim 19, from which claims 39 depends, has been addressed above. Claim 3 of U.S. Patent No. 6,280,589 B1 requires the body structure to be made from glass, a semiconductor material (which would suggest to one with ordinary skill in the art silicon), or a suitable polymer. Furthermore, Pace teaches a microfluidic device having a body structure made of silicon. See the abstract; Figures 1 and 3; and col. 5:35-60. It would have been obvious to one with ordinary skill in the art at the time of the invention to make the body structure from silicon as taught by Pace in the invention of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 as modified by Dubrow et al. (US 6,153,073) because as taught by Pace silicon offers a number of advantages, such as it is obtainable in useful dimensions and it has a high thermal conductivity. See col. 5:49-59.

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13. Claim 40 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073) and Pace (US 4,908,112). Claim 19, from which claim 40 depends, has been addressed above. Claim 3 of U.S. Patent No. 6,280,589 B1 requires the body structure to be made from glass, a semiconductor material (which would suggest to one with ordinary skill in the art silicon), or a suitable polymer. Furthermore, Pace teaches a microfluidic device having a body structure made of silicon. See the abstract; Figures 1 and 3; and col. 5:35-60. It would have been obvious to one with ordinary skill in the art at the time of the invention to make the body structure from silicon as taught by Pace in the invention of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 as modified by Dubrow et al. (US 6,153,073) because as taught by Pace silicon offers a number of advantages, such as it is obtainable in useful dimensions and it has a high thermal conductivity. See col. 5:49-59. Although not needed to meet the claim it should be noted that Dubrow discloses all of the claimed possible materials from which the body structure may be made. See claim 23 and col. 6:28-60. Besides the factors listed by Pace, one with ordinary skill in the art at the time of the invention would also consider chemical inertness of the body structure to the sample and electrolyte, transparency, and ease of manufacturing the channels and reservoirs in the body structure.

14. Claim 41 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073) and Pace (US 4,908,112). Claim 19,

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from which claim 40 depends, has been addressed above. Claim 3 of U.S. Patent No. 6,280,589 B1 requires the body structure to be made from glass, a semiconductor material (which would suggest to one with ordinary skill in the art silicon), or a suitable polymer. Furthermore, Pace teaches a microfluidic device having a body structure made of silicon. See the abstract; Figures 1 and 3; and col. 5:35-60. It would have been obvious to one with ordinary skill in the art at the time of the invention to make the body structure from silicon as taught by Pace in the invention of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 as modified by Dubrow et al. (US 6,153,073) because as taught by Pace silicon offers a number of advantages, such as it is obtainable in useful dimensions and it has a high thermal conductivity. See col. 5:49-59. Although not needed to meet the claim it should be noted that Dubrow discloses all of the claimed possible materials from which the body structure may be made. See claim 23 and col. 6:28-60. Besides the factors listed by Pace, one with ordinary skill in the art at the time of the invention would also consider chemical inertness of the body structure to the sample and electrolyte, transparency, and ease of manufacturing the channels and reservoirs in the body structure.

As for a first substrate having grooves, this is disclosed by Pace. See Figures 1-3. It would have been obvious to one with ordinary skill in the art at the time of the invention to make grooves in a first substrate as taught by Pace in the invention of the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073) because as taught by Pace a microchannel network can be precisely micromachined into a substrate having desirable properties using methods already generally applied in the semiconductor-microelectronics industry. See col. 5:35-59.

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As for a second substrate overlaying the first substrate, this is also disclosed by Pace. See col. 6:46-49. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a second substrate as taught by Pace in the invention of the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073) because this will protect the fluids from contamination.

15. Claim 42 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073) and Pace (US 4,908,112). Claim 41, from which claim 42 depends, has been addressed above. Since claim 42 only provides a product-by-process limitation. It does not further patentably limit claim 41 unless a material difference is shown between the product produced by the method of claim 42 and that disclosed by the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 as modified by Dubrow et al. (US 6,153,073) and Pace (US 4,908,112).

16. Claims 43 and 44 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073). Claim 19, from which claims 43 and 44 depend, has been addressed above. Dubrow discloses providing a sieving matrix or separation medium in the main channel. See claims 25 and 26; col. 15:37-46; and col. 18:1-27.

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It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a sieving matrix or separation medium as taught by Dubrow in the invention of the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 as modified by Dubrow because as taught by Dubrow the separation of the sample components will be enhanced. See col. 15:37-46; and col. 18:1-27.

17. Claim 45 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 in view of Dubrow et al. (US 6,153,073). Claim 19, from which claims 43 and 44 depend, has been addressed above. A voltage regulator as claimed is required by claims 3 and 4 of U.S. Patent No. 6,280,589 B1 since claim 1, from which they depend, requires that the “electric field [across the supply and drain channels] is applied for a period of time which is at least long enough that the component of said sample having the lowest electrophoretic mobility migrates into the geometrically defined sample volume, ...”

Double Patenting Rejections Based on US 6,423,198 B1

18. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 11 of U.S. Patent No. 6,423,198 B1 and Dubrow et al. (US 6,153,073). Although the conflicting claims are not

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identical, they are not patentably distinct from each other because the body structure set forth in claim 19 is implicitly or directly provided by claim 11 and the transport system set forth in claim 19 is implicitly provided by claim 4. The correspondence between the elements of claim 19 and claims 3 and 11 is as follows

<u>Claim 19(body structure)</u>	<u>Claim 11</u>
microfluidic device	micromachined or etched capillary channels
body structure	planar substrate
main channel	electrolyte channel
sample loading channel	supply channel
main channel intersecting the sample loading channel	supply and drain channels discharge into the electrolyte channel
sample loading channel is fluidly contains sample coupled to a source of at least one sample material and a fluid reservoir	sample plug is injected from the supply channel

<u>Claim 19(transport system)</u>	<u>Claim 3</u>
transport system coupled to the sample loading channel	electrokinetically injecting the sample
one or more control devices which direct movement of the at least one sample material through the sample loading channel to a position proximal to the intersection of the sample loading channel and the main channel	electrokinetically injecting the a sample plug into the electrolyte channel by applying an electric field across the supply and drain channels

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which one or more control devices concomitantly direct flow of material through the main channel

wherein said electrolyte buffer and said sample are transported electrokinetically, and further wherein immediately after said injection of said sample plug said electrolyte buffer is allowed to advance into said supply channel and into said drain channel

Even if the passage in claim 3 cited above as corresponding to the limitation to claim 19 of “which one or more control devices concomitantly direct flow of material through the main channel” is construed as not necessarily requiring concomitantly directing material flow through the main channel, it would have been obvious to one with ordinary skill in the art at the time of the invention to do so because as taught by Dubrow et al. (US 6,153,073), which implicitly discloses control means for injecting sample from a sample loading channel into main channel while concomitantly directly flow of material through the main channel, such control means will (a) “avoid any diffusion or leaking of the sample into the intersection during analysis,” and (b) saves time when multiple samples are analyzed. See the abstract; Figures 3, 2B, and 1A-1I; col. 13:8-15; and col. 14:52-65.

19. Claim 20 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073). Claim 19, from which claim 20 depends,

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has been addressed above. Electrosmotically or electrophoretically flowing an injected sample through at least a portion of the main channel while simultaneously loading an additional sample into the sample-loading channel is disclosed by Dubrow. See Figure 2B and col. 14:52-65. It would have been obvious to one with ordinary skill in the art at the time the invention was made to do so because as taught by Dubrow this will save time when multiple samples are to be processed. See col. 14:52-65. As for an instruction set for performing this activity see col. 5:33-40 in Dubrow. Furthermore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an instruction set for performing the claimed injecting step in the form of a computer program, for example, as this would be just merely automating control of the flow process.

20. Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073). Claim 19, from which claim 21 depends, has been addressed above. Electrosmotically or electrophoretically flowing an additional injected sample through at least a portion of the main channel while simultaneously loading a further additional sample into the sample-loading channel is disclosed by Dubrow. See Figure 2B and col. 14:52-65. It would have been obvious to one with ordinary skill in the art at the time the invention was made to do so because as taught by Dubrow this will save time when multiple samples are to be processed. See col. 14:52-65. As for an instruction set for performing this activity see col. 5:33-40 in Dubrow. Furthermore, it would have been obvious to one with

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ordinary skill in the art at the time the invention was made to provide an instruction set for performing the claimed injecting step in the form of a computer program, for example, as this would be just merely automating control of the flow process.

21. Claims 27-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 4, and 17 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073). Claim 22, from which claims 27-32 depend, has been addressed above. The combination of claims of 3 and 4 of U.S. Patent No. 6,423,198 B1 as modified by Dubrow (what portion is valid as prior art) does not mention the specific claimed “centers” for the reservoirs or density of the reservoirs, although claim 17 of U.S. Patent No. 6,423,198 B1 appears to disclose “centers” for the supply and drain ports of about 0 microns to 3 cm. In any event, the claimed “centers” and density, barring a contrary showing, is just a design choice. It would have been obvious to one with ordinary skill in the art at the time of the invention to have the reservoirs as close together as possible, without unduly lengthening the channel lengths so that the microfluidic device can be made as compact as possible without unnecessarily increasing the distance substances have to flow and while allowing ready access to the reservoirs.

22. Claims 27-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 4, and 17 of U.S.

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Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073). Claim 22, from which claims 27-32 depend, has been addressed above. Claim 17 of U.S. Patent No. 6,423,198 B1 appears to disclose “centers” for the supply and drain ports of about 0 microns to 3 cm. Also, Dubrow discloses the claimed reservoir centers and densities of reservoirs. See claims 9-13 of Dubrow. In light of these disclosures, the claimed “centers” and densities of reservoirs, barring a contrary showing, are just design choices. It would have been obvious to one with ordinary skill in the art at the time of the invention to have the reservoirs as close together as possible, such as disclosed by Dubrow, without unduly lengthening the channel lengths so that the microfluidic device can be made as compact as possible without unnecessarily increasing the distance substances have to flow and while allowing ready access to the reservoirs.

23. Claim 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073). Claim 22, from which claims 35 depends, has been addressed above. The combination of claims of 3 and 4 of U.S. Patent No. 6,423,198 B1 as modified by Dubrow (what portion is valid as prior art) does not mention having the widths and depths of the channels the same. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to do so because this will simplify manufacturing of the microfluidic device as only two aspects of a channel, the length and location, will have to be changed when a new channel is made.

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24. Claim 36 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 4, and 16 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073). Claim 22, from which claims 36 depends, has been addressed above. Claim 16 of U.S. Patent No. 6,423,198 B1 which is directed to a device for practicing the invention of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 requires the channels to have a depth within the claimed dimension range. Claim 18 of Dubrow requires the channels to also have a dimension as claimed. It would have been obvious to one with ordinary skill in the art at the time of the invention to have a dimension as claimed since the claimed device is a microfluidic device and the channel dimensions will be scaled according to the sample volume to be processed.

25. Claim 37 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 4, and 16 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073). Claim 22, from which claims 36 depends, has been addressed above. Claim 16 of U.S. Patent No. 6,423,198 B1 which is directed to a device for practicing the invention of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 requires the channels to have a depth overlapping the claimed depth dimension range. Claim 19 of Dubrow requires the channels to also have width and depth dimension ranges as claimed. It would have been obvious to one with ordinary skill in the art at the time of the invention to have a width and a depth within the dimension ranges claimed since the claimed device is a microfluidic device and the channel dimensions will be scaled according to the sample volume to be processed.

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26. Claim 38 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073). Claim 19, from which claims 38 depends, has been addressed above. The supply and drain ports of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 correspond to the sample reservoir and waste well, respectively, of claim 38 of the instant application and thus claim 38 provides a pre-loading module as claimed.

27. Claim 39 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 4, and 11 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073) and Pace (US 4,908,112). Claim 19, from which claims 39 depends, has been addressed above. Claim 11 of U.S. Patent No. 6,423,198 B1 requires the body structure to be made from glass, a semiconductor material (which would suggest to one with ordinary skill in the art silicon), or a suitable polymer. Furthermore, Pace teaches a microfluidic device having a body structure made of silicon. See the abstract; Figures 1 and 3; and col. 5:35-60. It would have been obvious to one with ordinary skill in the art at the time of the invention to make the body structure from silicon as taught by Pace in the invention of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 as modified by Dubrow et al. (US 6,153,073) because as taught by Pace silicon offers a number of advantages, such as it is obtainable in useful dimensions and it has a high thermal conductivity. See col. 5:49-59.

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28. Claim 40 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 4, and 11 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073) and Pace (US 4,908,112). Claim 19, from which claim 40 depends, has been addressed above. Claim 11 of U.S. Patent No. 6,423,198 B1 requires the body structure to be made from glass, a semiconductor material (which would suggest to one with ordinary skill in the art silicon), or a suitable polymer. Furthermore Pace teaches a microfluidic device having a body structure made of silicon. See the abstract; Figures 1 and 3; and col. 5:35-60. It would have been obvious to one with ordinary skill in the art at the time of the invention to make the body structure from silicon as taught by Pace in the invention of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 as modified by Dubrow et al. (US 6,153,073) because as taught by Pace silicon offers a number of advantages, such as it is obtainable in useful dimensions and it has a high thermal conductivity. See col. 5:49-59. Although not needed to meet the claim it should be noted that Dubrow discloses all of the claimed possible materials from which the body structure may be made. See claim 23 and col. 6:28-60. Besides the factors listed by Pace, one with ordinary skill in the art at the time of the invention would also consider chemical inertness of the body structure to the sample and electrolyte, transparency, and ease of manufacturing the channels and reservoirs in the body structure.

29. Claim 41 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 4, and 11 of U.S. Patent No.

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6,423,198 B1 in view of Dubrow et al. (US 6,153,073) and Pace (US 4,908,112). Claim 19, from which claim 40 depends, has been addressed above. Claim 11 of U.S. Patent No. 6,423,198 B1 requires the body structure to be made from glass, a semiconductor material (which would suggest to one with ordinary skill in the art silicon), or a suitable polymer. Furthermore, Pace teaches a microfluidic device having a body structure made of silicon. See the abstract; Figures 1 and 3; and col. 5:35-60. It would have been obvious to one with ordinary skill in the art at the time of the invention to make the body structure from silicon as taught by Pace in the invention of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 as modified by Dubrow et al. (US 6,153,073) because as taught by Pace silicon offers a number of advantages, such as it is obtainable in useful dimensions and it has a high thermal conductivity. See col. 5:49-59. Although not needed to meet the claim it should be noted that Dubrow discloses all of the claimed possible materials from which the body structure may be made. See claim 23 and col. 6:28-60. Besides the factors listed by Pace, one with ordinary skill in the art at the time of the invention would also consider chemical inertness of the body structure to the sample and electrolyte, transparency, and ease of manufacturing the channels and reservoirs in the body structure.

As for a first substrate having grooves, this is disclosed by Pace. See Figures 1-3. It would have been obvious to one with ordinary skill in the art at the time of the invention to make grooves in a first substrate as taught by Pace in the invention of the combination of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073) because as taught by Pace a microchannel network can be precisely micromachined into a substrate having desirable

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properties using methods already generally applied in the semiconductor-micorelectronics industry. See col. 5:35-59.

As for a second substrate overlaying the first substrate, this is also disclosed by Pace. See col. 6:46-49. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a second substrate as taught by Pace in the invention of the combination of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073) because this will protect the fluids from contamination.

30. Claim 42 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073) and Pace (US 4,908,112). Claim 41, from which claim 42 depends, has been addressed above. Since claim 42 only provides a product-by-process limitation. It does not further patentably limit claim 41 unless a material difference is shown between the product produced by the method of claim 42 and that disclosed by the combination of claims 3 and 4 of U.S. Patent No. 6,280,589 B1 as modified by Dubrow et al. (US 6,153,073) and Pace (US 4,908,112

31. Claims 43 and 44 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent

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No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073). Claim 19, from which claims 43 and 44 depend, has been addressed above. Dubrow discloses providing a sieving matrix or separation medium in the main channel. See claims 25 and 26; col. 15:37-46; and col. 18:1-27. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a sieving matrix or separation medium as taught by Dubrow in the invention of the combination of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 as modified by Dubrow because as taught by Dubrow the separation of the sample components will be enhanced. See col. 15:37-46; and col. 18:1-27.

32. Claim 45 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 4 of U.S. Patent No. 6,423,198 B1 in view of Dubrow et al. (US 6,153,073). Claim 19, from which claims 43 and 44 depend, has been addressed above. A voltage regulator as claimed is required by claims 3 and 4 of U.S. Patent No. 6,423,198 B1 since claim 1, from which they depend, requires that the “applying an electric field across said supply and drain channels for a period of time which is at least long enough, such that the injected sample plug reflects the original sample composition.”

Claim Rejections - 35 USC § 112

33. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

34. Claims 19-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

(a) The instant application claims priority from application serial no.'s 09/657,772 and 08/226,605 as a continuation of these applications (page 1 of the specification); however, the examiner has not found support in the instant application or the parent applications for the following limitation in claim 19 of the preliminary amendment of November 28, 2001 "which one or more control devices concomitantly direct flow of material through the main channel [while sample material is moved through the sample loading channel]." In fact, the specification of the instant application (which should be same as those in 09/657,772 and 08/226,605 since they are related as continuations) teaches away from this limitation, as it teaches having no voltage applied across the sample loading channel when a voltage is applied across the main channel and no voltage or a floating voltage across the main channel when a voltage is applied across the sample loading channel. See page 7, second full paragraph.

(b) Claim 25 of the preliminary amendment of November 28, 2001 requires at least eight reservoirs. No support has been found for this limitation. As seen in Figure 1, the second full paragraph on page 5, and the bottom paragraph on page 6 of the instant application only six reservoirs having specific functions and in a specific configuration with respect to each other are disclosed. There is no suggestion of adding other reservoirs. One with ordinary skill in the art at the time of the invention not know for what purpose the two additional reservoirs are to be used and where to locate them relative to the main channel, the detectors, and the other reservoirs.

(c) Claims 27-32 have requirements for reservoir “centers” and density of reservoirs for which no support has been found in the specification of the instant application or either of the parent applications.

(d) Claims 36 and 37 have dimensional limitations for which no support has been found in the specification of the instant application or either of the parent applications.

(e) Claims 40 and 41 recite a large number of materials from which the body structure may be made for which no support has been found in the specification of the instant application or the disclosures of the parent applications. The specification of the instant application only states, “the sampling device is integrated into a system of capillary channels which are established in a small planar sheet of glass, semiconductor material, or a suitable polymer [emphasis added].” See page 10, second full paragraph.

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(f) Claim 42 requires the grooves to be embossed or etched. No support has been found in the specification of the instant application or the disclosures of the parent applications for this limitation. The specification of the instant application only states, “the sampling device is integrated into a system of capillary channels which are established in a small planar sheet of glass, semiconductor material, or a suitable polymer [emphasis added].” See page 10, second full paragraph.

(g) Claims 43 and 44 require the main channel to comprise a separation medium or a sieving medium. No support has been found in the specification of the instant application or the disclosures of the parent applications for these limitations.

(h) Claim 45 allows for the one or more control devices to be a pressure regulator or a hydrodynamic force regulator. No support has been found in the specification of the instant application or the disclosures of the parent applications for these limitations.

35. Claims 19-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

(a) Claim 19, which is the only independent claim, has the limitation “which one or more control devices concomitantly direct flow of material through the main channel [while sample

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material is moved through the sample loading channel].” However, the specification teaches a contrary manner of operating the microfluidic device. Page 7, second full paragraph of the specification teaches having no voltage applied across the sample loading channel when a voltage is applied across the main channel and no voltage or a floating voltage across the main channel when a voltage is applied across the sample loading channel. One with ordinary skill in the art at the time of the invention would not know how to make/use a claimed invention that is contrary to what is taught by the specification.

(b) Claim 25 of the preliminary amendment of November 28, 2001 requires at least eight reservoirs. As seen in Figure 1, the second full paragraph on page 5, and the bottom paragraph on page 6 of the instant application only six reservoirs having specific functions and in a specific configuration with respect to each other are disclosed. One with ordinary skill in the art at the time of the invention not know for what purpose the two additional reservoirs are to be used and where to locate them relative to the main channel, the detectors, and the other reservoirs.

(c) Claim 26 of the preliminary amendment of November 28, 2001 requires at least eight reservoirs, wherein four of the reservoirs are on one side of the main channel and four of the reservoirs are on the other side of the main channel. As seen in Figure 1, the second full paragraph on page 5, and the bottom paragraph on page 6 of the instant application only six reservoirs having specific functions and in a specific configuration with respect to each other are disclosed. One with ordinary skill in the art at the time of the invention not know for what

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purpose the two additional reservoirs are to be used and where to locate them relative to other reservoirs and the detectors.

36. Claim 45 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a voltage regulator, does not reasonably provide enablement for a pressure regulator or a hydrodynamic force regulator. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification and drawings of the instant application only describes an improved method for electrokinetically injecting a sample plug into a microchannel. No mention is made of a pressure regulator or a hydrodynamic force regulator. One with ordinary skill in the art at the time of the invention would not know how to use improvements in using an electric field to inject a sample plug to improving use of pressure or a hydrodynamic force to inject a sample plug.

37. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

38. Claims 21, 23-26, 33, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 21 recites the limitation "the additional sample" in line 2. There is insufficient antecedent basis for this limitation in the claim;

b) Claim 23: are the at least six reservoirs in addition or including the at least three reservoirs of claim 22? Is the at least one of the six reservoirs of claim 23 the same as the at least one of the three reservoirs of claim 22?

c) Claim 25: are the at least eight reservoirs in addition or including the at least three reservoirs of claim 22? Is the at least one of the eight reservoirs of claim 25 the same as the at least one of the three reservoirs of claim 22?

d) Claims 27-29: no definition of “centers” as used in these claims has been found. Does “centers” mean the spacing between the centers of adjacent reservoirs?

e) Claim 33: are the at least four reservoirs in addition or including the at least three reservoirs of claim 22?

f) Claim 38: are the sample reservoir and waste reservoir in addition to the fluid reservoir of claim 19?

39. Note that dependent claims will have the deficiencies of base and intervening claims.

Specification

40. The abstract should be 150 words or less.

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41. Applicants should amend the title by replacing "Method for" with -- Microfluidic device configured for -- as no method claims are pending.

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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February 16, 2005